

**PHARMACY EXAMINING BOARD
APRIL 7, 2010
MEETING MINUTES**

- PRESENT:** Pamela Phillips; Amy Mattila, R.Ph; Jeanne Severson, R.Ph., Jason Walker-Crawford, R.Ph.; Suzette Renwick; and Gregory C. Weber, R.Ph.
- EXCUSED:** Timothy Boehmer, R.Ph.
- STAFF:** Gail Sumi, Bureau Director; Michele Miller Hayes, DRL Board Counsel; Michelle Solem, Bureau Assistant; and other DRL Staff
- GUESTS:** Jeff Burkhamer, Brad Shaw, and Stefan Lindberg, JAT Pharmacy; Gary Plank, Marshfield Clinic; Robert Block, Controlled Substances Board; David McAllister; Lisa Sobotkiewicz, Target Pharmacy; Eric Knox, Wisconsin Department of Corrections (DOC); Donnalee Hustedt and Lennet Radke, Ministry Home Care; Teresa Geier, Walmart Pharmacy; Dean Polar, Cardinal Health; Matt Wilson, DVM, Midwest Veterinary Supply; Carol Petersen, Women's International Pharmacy; Matt Mabie, Hometown Pharmacy; Erik Bauch, Brian McIlhone and Liz Green, Walgreens Pharmacy; Hashim Zaibak, CVS Pharmacy; Jeremy Levin, Rural Health Wisconsin Cooperative (RWHC); Tom Engels, Pharmacy Society of Wisconsin; and Laurie Flagel Dean, Group Health Cooperative

CALL TO ORDER

Jeanne Severson, Board Chair, called the meeting to order at 9:01 a.m. A quorum of 6 members was confirmed.

APPROVAL OF AGENDA

Amendments:

- Page numbers on Q should include 111
- Remove Jason Walker-Crawford from the screening panel and add Greg Weber
- Under Monitoring on page 6, Kurt Kiesling will not be appearing today but most likely at the next meeting
- Review and take action on the DEA/Nursing Home Issue
- Consider adoption of one additional scope statement

MOTION: Suzette Renwick moved, seconded Amy Mattila, to approve the agenda as amended. Motion carried unanimously.

APPROVAL OF MINUTES OF FEBRUARY 3, 2010

Corrections:

- Include "question writing workshop" in the MPJE section
- Revise guest to "Access Community Health Centers"
- White pages should read "White Papers" on page three in section related to web-site

- With respect to the Travel Section – the motion should read “designate Amy Mattila as delegate”
- Add an “E” to “ACP” in the administrative rules section
- The pandemic flu preparedness should read “extension of the distribution of pandemic flu counter measures”
- Under Quality Review Report – Capitalize “Board”
- Should read “National Association of Boards of Pharmacy”
- Under Alan Dickman – correct the motion.
- Remote Dispensing – middle third paragraph – Legislature should be capitalized

MOTION: Amy Mattila moved, seconded by Jason Walker-Crawford, to approve the February 3, 2010 minutes as amended. Motion carried unanimously.

APPROVAL OF MINUTES OF FEBRUARY 16, 2010

Corrections:

- Capitalize “Legislature” in the motion
- Change the motion – Amy Mattila and Tim Boehmer voted in opposition

MOTION: Amy Mattila moved, seconded by Jason Walker-Crawford, to approve the February 16, 2010 minutes as amended. Motion carried unanimously.

PRESENTATION OF PROPOSED STIPULATIONS

LLOYD SCHAEFER, R.PH.

Attorney Sandra Nowack presented the Proposed Stipulation, Final Decision and Order in the matter of Lloyd Schaefer, R.Ph.. Deliberation will be in closed session.

COMMUNITY HOME MEDICAL EQUIPMENT

Attorney Sandra Nowak presented the Proposed Stipulation, Final Decision and Order in the matter of Community Home Medical Equipment. Deliberation will be in closed session.

ALLAN T. MAILLOUX, R.PH.

Attorney Jeanette Lytle presented the Proposed Stipulation, Final Decision and Order in the matter of Allan T. Mailloux, R.Ph.. Deliberation will be in closed session.

REEDSBURG AREA MEDICAL CENTER

Attorney Jim Polewski presented the Proposed Stipulation, Final Decision and Order in the matter of Reedsburg Area Medical Center. Deliberation will be in closed session.

ADMINISTRATIVE REPORT

Staff Update

Jeanne Severson introduced Michele Miller Hayes as the new legal counsel for the Board. Ms. Severson also thanked Michael Berndt for his service during his tenure as interim legal counsel. She also reviewed the information included in the red folders. She received a document from the Drug Enforcement Administration related to *Electronic Prescriptions for Controlled Substances*. There is a 60 day comment period for this rule. The comment period could end as early as June 1. The next scheduled meeting of the Pharmacy Examining Board is June 2. Jason Walker-Crawford indicated that there may be some implications for the Board based on his review of the document. Ms. Severson asked the Board if they would be willing to participate in a teleconference to formulate comments that the Board would like to submit. The Board was asked to send their thoughts related to a possible teleconference to Gail Sumi.

Late Adds

Gail Sumi conducted a brief review of the late adds policy.

Update of Board Web Pages on DRL Website – Appoint Reviewers

Ms. Sumi asked if the Members would review the website and forward any changes, corrections or deletions to her at the next meeting. She also indicated that she has received requests for previous copies of the Regulatory Digests.

REPORT ON AND REQUEST FOR SPEAKING ENGAGEMENTS

Report on PSW Legislative Day Presentation, February 24, 2010 by Greg Weber

Greg Weber indicated that the presentation went well. He shared the comments from the meeting with the members and briefly described Legislative Day activities. Greg Weber's presentation will be posted to the website with the effective dates for the rules changed to reflect the June 1, 2010 effective date.

Request by Professor Walbrandt Pigarelli for a PEB Speaker to Address the Advanced Clerkship Seminar at UW-Madison School of Pharmacy

Jeanne Severson indicated that these items will continue to be discussed by the Board. Mr. Weber suggested that the presentation that he made this year and the presentation that Tim Boehmer created last year could be merged to create the update that they are requesting.

MOTION: Pamela Phillips moved, seconded by Suzette Renwick, to designate Jason Walker-Crawford as the speaker and Jeanne Severson as the alternate for the presentation at the UW-Madison School of Pharmacy. Motion carried unanimously.

VARIANCE REQUEST FORT HEALTHCARE

Jeanne Severson explained this variance request to the Board in lay terms. Mr. Walker-Crawford noted that he liked the look of the new forms but would like to see more documentation than was provided with this request. He also noted that if the variance would be granted, he would prefer to have a 10% pharmacist check of the controlled substances. Mr. Weber indicated the Board is not able to grant this variance and that was also the opinion of Michele Miller Hayes.

MOTION: Greg Weber moved, seconded by Jason Walker-Crawford, to deny the Automated Dispensing variance request due to the fact that the Board does

not have the authority to grant a variance under PHAR 7.09. Motion carried unanimously.

VARIANCE REQUEST MINISTRY HOSPICE

Donna Husted and Lanette Radtke, representatives from Ministry Hospice, described this facility as a free standing inpatient hospice facility for acute needs that could not be fulfilled in the home. The request is not for in home medication but for use within the facility. After much discussion, the Board decided that PHAR 7.09 (1) (b) has outdated language that should be updated to include hospice facilities. The Board agreed that this situation would qualify as an inpatient facility which would allow the Board to grant this variance. The Board came to the consensus that there are several questions that need to be answered and issues addressed before this variance request will be considered. The Board tabled the final decision until the information has been received.

PRESCRIPTION DRUG MONITORING PROGRAM ROBERT BLOCK, WISCONSIN STATE CRIME LAB

Robert Block reported that AB 227 is out of committee and is expected to be in the Governor's office very soon. He will be attending a national conference related to the program and offered to relay comments and ask questions on behalf of the Board.

He outlined the process by which the Board could write rules to address this program. He also suggested some financial assistance that might be available. The Board discussed the intent of the Legislature to delay rule writing until funding is received.

Ms. Sumi indicated that the Board could have guest speakers at Board meetings and outreach meetings to create an awareness of the new legislation. She also suggested that the Board consider including guest speakers for future Board meetings. She reported that the Department will be hiring someone to write a grant application to request the funds needed to launch this program. It was noted that it is understood that it was the intent of the Legislature that rule making related to the drug monitoring program not begin until such time as the funding has been received. Jeanne Severson suggested that this Board also consider outreach to prescribers.

LEGISLATIVE LIAISON REPORT JASON WALKER-CRAWFORD

Jason Walker-Crawford distributed a report outlining the legislative activity of bills related to the Pharmacy Examining Board. He also distributed a copy of 2009 SB 657 which defines abuse and neglect of patients and residents.

ADMINISTRATIVE RULES

CR09-098

Ms. Severson offered to help Ms. Sumi draft a notice for the website.

MOTION: Greg Weber moved, seconded by Amy Mattila, to adopt CR09-098 related to security systems, utilization reviews and prescription orders transmitted by facsimile machine. Motion carried unanimously.

CR 09-099

Ms. Severson noted that these changes went into effect on April 1, 2010. Any variance that was in place has expired with the new legislation. They will now be required to comply with the new rules.

Remote Dispensing Site Notice Form

The Board suggested the following changes to the Remote Dispensing Site form that was submitted by the Department.

- Delete the sentence that states “subject to amendment” after the first bullet point since the rule has been adopted.
- Remove “WI” from in front of supervising pharmacy
- Where it is noted in the first bullet point that the “RDS shall not deliver”, the form should be changed to say dispense.
- The first bullet point under managing pharmacist refers to 7.09 should be 7.095.
- Under “C” on the back page, there should be an “a” under conduct “a” controlled substance inventory and “the” to insure that “the” RDS personnel comply.

Scope Statement re: PHAR 1.02(7)

This will correct nomenclature for NAPLEX and ACPE. This item will be brought back on the next agenda based on the language in the statutes.

Scope Statement re: Introductory Pharmacy

The Board discussed changing the statement to better reflect the intent of the Board. Ms. Sumi will work with Mr. Walker-Crawford to change the definition of required hours from intern hours to practical experience hours and better define the difference between introductory hours and advanced hours. A representative from the ACPE was here and informed the Board that they are in the process of review and making changes to the definitions and expect to have those changes by the end of the year.

REVIEW of CURRENT AND FUTURE RULEMAKING AND LEGISLATIVE INITIATIVES

It was noted the items listed under “Current rulemaking” have been completed. Under future rulemaking, the Board decided to address items 1-3 in September or October and to leave item 4 at the bottom of the priority list. The Board also decided to drop activity related to the Wisconsin Department of Justice drug disposal project until the bill is reintroduced in the Legislature. The Board suggested that revisions to PHAR 7.09 be added to potential rulemaking for review sometime in the future.

REGULATORY DIGEST

Mr. Weber indicated that he has received a deadline for the Regulatory Digest from Secretary Jackson. He asked for guidance related to the party responsible for preparing the Digest. Ms. Sumi indicated that the draft copy should be sent electronically to the Board. She also indicated

that we have received communication from the Department of Public Instruction that should be included in a future Digest. The Board also discussed including all discipline that has been included in the previous issues.

PRACTICE QUESTIONS

Prescription Drug Disposal

It was noted that the pharmacy can take back medications as long as they are disposed of and not resold provided they are not a controlled substance. (Ref. PHAR 7.04)

Quantity or Days Supply Limit When Dispensing Controlled Substances

Mr. Walker-Crawford indicated that he had received this questions many times. Ms. Severson noted that these questions may be stemming from changes in neighboring states and changes published by the DEA. Prescriptions are only good for 60 days from the date it was written.

Electronic Nicotine Delivery Devices – E-Cigarettes

Mr. Walker-Crawford indicated that the Board does not have jurisdiction to restrict the distribution of this item until the FDA rules that this product is a drug product or prescription only product.

SUMMARY REPORT ON ADMINISTRATIVE RULES

Noted.

VARIANCE REQUESTS AND REPORTS RECEIVED IN THE BUREAU AFTER MAILING OF THE AGENDA

None.

BOARD REVIEW OF CURRENT AND FUTURE RULEMAKING AND LEGISLATIVE INITIATIVES – DISCUSS AND SET PRIORITIES

DOE INSPECTION LIAISON REPORT AMY MATTILA

No report at this time.

CREDENTIALING LIAISON REPORT TIMOTHY BOEHMER

No report at this time.

QUALITY REVIEW COUNCIL REPORT JEANNE SEVERSON

Jason Walker-Crawford has corresponded with the Pharmacy Schools to inform them that a representative from the board will no longer participate.

**STATE COUNCIL ON ALCOHOL AND OTHER
DRUG ABUSE (SCAODA) REPORT
PAMELA PHILLIPS**

No report at this time. The meeting is scheduled for next week. Jeanne Severson appointed Pamela Phillips as the delegate and Suzette Renwick as the alternate.

**NATIONAL ASSOCIATION OF BOARDS OF PHARMACY
COMMITTEE ON LAW ENFORCEMENT/LEGISLATION MEETING
AMY MATTILA**

No report at this time.

**DRUG ENFORCEMENT ADMINISTRATION
MONTHLY DRUG THEFT AND LOSS REPORTS.**

Noted.

**APPLICATION REVIEW
JAT PHARMACY, LLC**

Jeff Burkhamer and Brad Shaw provided an overview of the pharmacy model that they would like to develop. JAT Pharmacy is a wholly owned subsidiary of Midwest Veterinary Supply. The Sun Prairie facility is currently a wholesale distributor for veterinary medication selling only to licensed veterinarians. Currently, they are only able to market to the veterinarian and this request, if granted, would enable them to ship the medication to the end user thus eliminating the veterinarian as the middleman for dispensing purposes.

MEDCO AT HOME

Dennis McAllister and Nevin Okey provided an overview of the pharmacy model that they would like to develop. They are asking that they obtain a license to practice following the model set forth in 5 other states. They would like to expand the workforce. This model completes all tasks of a physical pharmacy with the exception of dispensing medication which is done via automated closed system. They would like to be licensed as a pharmacy to provide their clients with the assurance of compliance. They noted that their facilities would be open to inspectors from the Department.

INFORMATIONAL ITEMS

The Board discussed a memo from NABP related to Controlled Substance Dispensing Issues for Long Term Care Facilities. They discussed that if the Board were to submit a formal letter indicating that the Board believes that the Nursing Homes are able to dispense and therefore eligible for DEA registration. The changes that the DEA is recommending would allow for additional opportunities for diversion.

MOTION: Jason Walker-Crawford moved, seconded by Suzette Renwick, to ask the Department to collaborate with DHS to draft a letter in support of DEA registration for long term care facilities in the state of Wisconsin. Motion carried unanimously.

PUBLIC COMMENTS

None.

CLOSED SESSION

MOTION: Suzette Renwick moved, seconded by Jason Walker-Crawford, to convene to closed session to deliberate on case(s) following hearing (Wis. Stat. § 19.85 (1) (a)); consider closing disciplinary investigation(s) with administrative warning(s) (Wis. Stat. § 19.85 (1) (b) and 440.205); to consider individual histories or disciplinary data (Wis. Stat. § 19.85 (1) (f)); and to confer with legal counsel (Wis. Stat. § 19.85 (1) (g)). Roll Call Vote: Pamela Phillips-yes; Suzette Renwick-yes; Jason Walker-Crawford-yes; Gregory C. Weber-yes; Jeanne Severson-yes; Amy Mattila - yes. Motion carried unanimously.

Open session recessed at 2:28 p.m.

RECONVENE TO OPEN SESSION

MOTION: Suzette Renwick moved, seconded by Greg Weber, to reconvene into open session at 4:33 p.m. Motion carried unanimously.

VOTING ON ITEMS CONSIDERED/DELIBERATED IN CLOSED SESSION

PROPOSED STIPULATIONS, FINAL DECISIONS AND ORDERS

08 PHM 045

LLOYD G. SCHAEFER, R.PH.

MOTION: Greg Weber moved, seconded by Jason Walker-Crawford, to adopt the Findings of Fact, Conclusions of Law, Stipulation and Order, in the matter of Lloyd G. Schaefer, R.Ph.. Motion carried unanimously.

09 PHM 007

ALLAN T. MAILLOUX, R.PH.

MOTION: Jason Walker-Crawford moved, seconded by Suzette Renwick, to adopt the Findings of Fact, Conclusions of Law, Stipulation and Order, in the matter of Allan T. Mailloux, R.Ph.. Motion carried unanimously.

09 PHM 012
COMMUNITY HOME MEDICAL EQUIPMENT, LLC

MOTION: Greg Weber moved, seconded by Suzette Renwick, to adopt the Findings of Fact, Conclusions of Law, Stipulation and Order, in the matter of Community Home Medical Equipment, LLC. Motion carried unanimously.

09 PHM 040
REEDSBURG AREA MEDICAL CENTER

MOTION: Amy Mattila moved, seconded by Jason Walker-Crawford, to adopt the Findings of Fact, Conclusions of Law, Stipulation and Order, in the matter of Reedsburg Area Medical Center. Motion carried unanimously.

CASE CLOSINGS

08 PHM 048

MOTION: Pamela Phillips moved, seconded by Amy Mattila, to close case 08 PHM 048 for insufficient evidence. Motion carried unanimously.

MONITORING

HEIDI TIMMERMAN, R.PH.
REQUESTING STAY AND MODIFICATION

MOTION: Jason Walker-Crawford moved, seconded by Amy Mattila, to grant Heidi Timmerman's request of 20 PIC hours and the ability to open and close a pharmacy consecutively. Motion carried unanimously.

JEREMY VAN BUREN, R.PH.
REQUESTING MODIFICATIONS

MOTION: Suzette Renwick moved, seconded by Amy Mattila, to grant Jeremy Van Buren's request for a reduction of therapy to one time per month and allow for a total of 16 PIC hours. Motion carried. Jason Walker-Crawford abstained.

GILLIAM SANFORD, R.PH.
REQUESTING FULL LICENSURE

MOTION: Pamela Phillips moved, seconded by Jason Walker-Crawford, to grant Gilliam Sanford's request for full licensure. Motion carried unanimously.

**BONNIE KIMBALL, R.PH.
REQUESTING PIC HOURS**

MOTION: Suzette Renwick moved, seconded by Jason Walker-Crawford, to deny Bonnie Kimball's request for 20 PIC hours and a reduction in drug screens to 75 times per year and require submission of documentation explaining missed calls, submit all prescription records for active prescriptions and submit work reports from all employers. Motion carried unanimously.

APPLICATION REVIEW

**JAT PHARMACY, LLC.
APPLICATION REVIEW**

MOTION: Pamela Phillips moved, seconded by Suzette Renwick, to request additional information from JAT Pharmacy, LLC and refer to the credentialing liaison. Motion carried unanimously.

**MEDCO AT HOME
PHARMACY APPLICATION**

No action taken.

**MICHAEL A. ROTH
RECIPROCAL APPLICATION**

MOTION: Amy Mattila moved, seconded by Jason Walker-Crawford, to approve Michael A. Roth to take the MPJE exam and issue a license based on successful completion of all requirements. Motion carried unanimously.

**LESTER PAULSON
RE-REGISTRATION APPLICATION**

MOTION: Jason Walker-Crawford moved, seconded by Amy Mattila, to grant re-registration to Lester Paulson upon successful completion of the MPJE. Motion carried unanimously.

ADJOURNMENT

MOTION: Suzette Renwick moved, seconded by Amy Mattila, to adjourn the meeting at 4:37 p.m. Motion carried unanimously.